AMENDMENT UNDER 37 C.F.R. § 1.116

Application No.: 10/777,683

**AMENDMENTS TO THE CLAIMS** 

This listing of claims will replace all prior versions and listings of claims in the

Attorney Docket No.: Q74236

application:

LISTING OF CLAIMS:

1. (currently amended): A method for assessment of possibility of diagnosis of or

determination of the presence or absence of risk for or assessment of the level of the risk of

cystic lung fibrosis in humans, comprising measuring the level of native CAP 18 in a biological

sample, wherein the biological sample is expectoration or bronchoalveolar lavage fluid (BALF),

and correlating comparing the measurement with cystic lung fibrosis by an increase in the level

of said CAP 18 in the biological sample withas compared to the level of native CAP 18 in a

control sample, whereby an increase in the level of CAP 18 in the biological sample as compared

to the control indicates a possible diagnosis of or a possible presence of risk for or increased

level of risk for cystic lung fibrosis, and genotypically or phenotypically confirming the

diagnosis or the determination of the presence or absence of risk or assessment of the level of the

risk wherein said CAP 18 specifically reacts with an antibody that specifically reacts with a

protein having an amino acid sequence of SEQ ID NO: 1, 2, 3 or 4.

2.-3. (canceled).

4. (original): The method according to claim 1, wherein the level of CAP 18 is measured

through antigen-antibody reaction.

2

AMENDMENT UNDER 37 C.F.R. § 1.116 Attorney Docket No.: Q74236

Application No.: 10/777,683

5. (original): The method according to claim 4, wherein the measurement through antigen-antibody reaction employs an antibody capable of binding to a peptide having an amino acid sequence of SEQ ID NO: 1.

- **6. (original):** The method according to claim 4, wherein the measurement through antigen-antibody reaction employs a solid phase.
- 7. (previously presented): The method according to claim 6, wherein the measurement through antigen-antibody reaction employing a solid phase is performed through a method comprising the following steps (a) to (c):
- (a) a step of bringing the sample into contact with a solid phase, to thereby immobilize onto the solid phase CAP 18 contained in the sample;
- (b) a step of causing the immobilized CAP 18 obtained in step (a) to be bound to an antibody capable of binding to a peptide having an amino acid sequence of SEQ ID NO: 1, to thereby form a complex of the two components; and
  - (c) a step of detecting the complex formed in step (b).
- 8. (previously presented): The method according to claim 6, wherein the measurement through antigen-antibody reaction employing a solid phase is performed through a method comprising the following steps (a)' and (b)':
- (a)': a step of bringing into mutual contact the following three components: a solid phase to which a first antibody capable of binding to a peptide having an amino acid sequence of SEQ ID NO: 1 has been immobilized, the sample, and a second antibody capable of binding to a

AMENDMENT UNDER 37 C.F.R. § 1.116

Application No.: 10/777,683

peptide having an amino acid sequence of SEQ ID NO: 1, to thereby form a sandwich-like

complex formed of first antibody immobilized onto a solid phase - CAP 18 - second antibody;

Attorney Docket No.: Q74236

and

(b)' a step of detecting the sandwich-like complex formed in step (a)'.

9.-10. (canceled).

11. (original): The method according to claim 21, wherein the level of CAP 18 is

measured through antigen-antibody reaction.

12. (original): The method according to claim 11, wherein the measurement through

antigen-antibody reaction employs an antibody capable of binding to a peptide having an amino

acid sequence of SEQ ID NO: 1.

13. (original): The method according to claim 11, wherein the measurement through

antigen-antibody reaction employs a solid phase.

14. (previously presented): The method according to claim 13, wherein the

measurement through antigen-antibody reaction employing a solid phase is performed through a

method comprising the following steps (a) to (c):

(a) a step of bringing the sample into contact with a solid phase, to thereby immobilize

onto the solid phase CAP 18 contained in the sample;

4

AMENDMENT UNDER 37 C.F.R. § 1.116 Attorney Docket No.: Q74236

Application No.: 10/777,683

(b) a step of causing the immobilized CAP 18 obtained in step (a) to be bound to an

antibody capable of binding to a peptide having an amino acid sequence of SEQ ID NO: 1, to

thereby form a complex of the two components; and

(c) a step of detecting the complex formed in step (b).

15. (previously presented): The method according to claim 13, wherein the

measurement through antigen-antibody reaction employing a solid phase is performed through a

method comprising the following steps (a)' and (b)':

(a)': a step of bringing into mutual contact the following three components: a solid phase

to which a first antibody capable of binding to a peptide having an amino acid sequence of SEQ

ID NO: 1 has been immobilized, the sample, and a second antibody capable of binding to a

peptide having an amino acid sequence of SEQ ID NO: 1, to thereby form a sandwich-like

complex formed of first antibody immobilized onto a solid phase - CAP 18 - second antibody;

and

(b)' a step of detecting the sandwich-like complex formed in step (a)'.

16. (canceled).

17. (withdrawn-amended): A kit for diagnosis of, determination of the presence or

absence of risk of, assessment of the level of the risk of, assessment of severity and/or acuteness

of, or assessment regarding progress of cystic lung fibrosis, comprising the following

components (A) and (B):

(A) a solid phase, and

5

AMENDMENT UNDER 37 C.F.R. § 1.116 Attorney Docket No.: Q74236

Application No.: 10/777,683

(B) an antibody capable of binding to a peptide having an amino acid sequence of SEQ ID NO: 1.

18. (withdrawn-amended): A kit for assessment of possibility diagnosis of, determination of the presence or absence of risk of, assessment of the level of the risk of, assessment of severity and/or acuteness of, or assessment regarding progress of cystic lung fibrosis, comprising the following components (A)' and (B)':

(A)': a solid phase to which a first antibody capable of binding to a peptide having an amino acid sequence of SEQ ID NO: 1 has been immobilized, and

(B): a second antibody capable of binding to a peptide having an amino acid sequence of SEQ ID NO: 1.

## 19.-20. (canceled).

- 21. (new): the method of claim 1, wherein said native CAP 18 consists of the amino acid sequence of SEQ ID NO:4.
- 22. (new): A method for assessment of severity and/or acuteness of or assessment regarding progress of cystic lung fibrosis in humans, comprising measuring the level of native CAP 18 in a biological sample, wherein the biological sample is expectoration or bronchoalveolar lavage fluid (BALF), comparing the level of said CAP 18 in the biological sample with the level of CAP 18 in a control sample, whereby an increase in the level of CAP 18

AMENDMENT UNDER 37 C.F.R. § 1.116

Application No.: 10/777,683

Attorney Docket No.: Q74236

in the biological sample as compared to the control indicates an increase in the severity and/or acuteness of or progress of cystic lung fibrosis.

23. (new): The method of claim 22, wherein said native CAP 18 consists of the amino acid sequence of SEQ ID NO:4.